510(k) Summary
VISUALIZATION TECHNOLOGY, INC.
INSTATRAK SYSTEM
WITH FLUOROCAT

## 1. SPONSOR

Visualization Technology, Inc.
200 Research Drive
Wilmington, MA 01887
Telephone: (978) 933-1000

Primary Contact: Norma LeMay
Sr. Regulatory Affairs Coordinator

Secondary Contact: Peter Ohanian
Vice President, Quality Assurance & Regulatory Affairs

## 2. DEVICE NAME

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|---|---|
| Proprietary Name: | InstaTrak System with FluoroCAT |
| Common/Usual Name: | Interactive Image Guided Surgical System |
| Classification Name: | Computed Tomography X-Ray System |

## 3. PREDICATE DEVICES

- Visualization Technology Inc., InstaTrak System with FluoroCAT, K994270, FDA concurrence received March 9, 2000
- General Electric Medical Systems, Advantage 3D XR, K974715, FDA concurrence received July 6, 1998

## 4. DEVICE DESCRIPTION

The InstaTrak System is an image guidance system indicated for use during sinus, skull base, cranial and axial skeletal procedures. The InstaTrak system with FluoroCAT is similar to the InstaTrak System with FluoroTrak cleared under



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K994270. The changes to the system include software enhancements to allow for the 3D image reconstruction. Using the InstaTrak system, the surgeon can readily identify the immediate location and position of the surgical instrument during the indicated procedure. The InstaTrak system assists the surgeon in avoiding critical nerves and other anatomical structures.

The original InstaTrak system allows the user to view the medical images of the patient's anatomy in response to the mouse or the tracked surgical instrument. Alignment of the patient and images is accomplished through the registration process. In all types of surgery the goal is the same, to indicate to the surgeon based on the pre-operative medical images, where the position of a tracked surgical tool is with regard to the patient's anatomy. The InstaTrak system with FluoroCAT is based on the same hardware and software used in the current InstaTrak System and provides all of the above features. It utilizes the same clinically proven electromagnetic tracking technology as its predecessor.

## 5. INTENDED USE

The system is intended as an aid to the surgeon for precisely locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, cranial, long bone, or vertebra, visible on medical images such as CT, MR, or X-ray.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The FluoroCAT is essentially identical in technological characteristics to the FluoroTrak module cleared under K994270 with the exception of software enhancements to allow for the 3D reconstruction. However, the 3D volumetric reconstruction method used is similar to the Advantage 3D XR manufactured by GE Medical Systems (K974715, FDA concurrence received July 6, 1998).
In addition, the FluoroCAT uses the same electromagnetic position sensing, and registration process as the FluoroTrak cleared under K994270.

The principles of operation for the FluoroCAT are identical to that described in K994270. The FluoroCAT and the FluoroTrak both use a Sun Ultra 10 workstation computer, flat panel display touch screen, hard disk storage system, software and an electromagnetic tracking system. Both applications offer image guidance using X-ray medical images.

The Visualization Technology, Inc. FluoroCAT is substantially equivalent to the current InstaTrak System with FluoroTrak, cleared under K994270, and the Advantage 3D XR manufactured by General Electric Medical Systems, subject of K974715. The only difference between the FluoroTrak module and FluoroCAT is software enhancements to allow for the 3D image reconstruction. However, the 3D volumetric reconstruction method used is similar to the Advantage 3D XR manufactured by GE Medical Systems (K974715, FDA concurrence received July 6, 1998).

## 7. PERFORMANCE TESTING

Testing was performed on the InstaTrak system with FluoroCAT, demonstrating that the device performed within specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2001

Mr. Norma J. LeMay
Sr. Regulatory Affairs Coordinator
Visualization Technology, Inc.
200 Research Drive
WILMINGTON MA 01887

Re: K003510
InstaTrak™ System with FluoroCat™ Model IT3500
Dated: November 10, 2000
Received: November 14, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. LeMay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

*510(k) Number (if known):* K003510

*Device Name:* *Visualization Technology, Inc. InstaTrak System with FluoroCAT™*

*Indications For Use:*

*The system is intended as an aid to the surgeon for precisely locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, cranial, a long bone or vertebra, visible on medical images such as CT, MR, or X-ray.*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Lynn

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, ENT, and Radiological Devices**
**510(k) Number** K003510